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10/050,238	01/16/2002	Michael Paul Aronson	J6699/1(C)	6809

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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/050,238

Applicant(s)

ARONSON ET AL.

Examiner

Shobha Kantamneni

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-7,9-13,15-17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 4-7,9-13,15-17,19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment received on 05/03/2007, wherein claims 5, 22 have been amended.

Applicant's amendment overcomes the rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for insufficient antecedent basis.

Claims 4-7, 9-13, 15-17, and 19-23 are pending, and examined herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "droplet size of the structured oil-in-water greater than 100 to 500 microns" in the claim. It is not clear if the applicant intends to mean droplet size of greater than 100 and less than or equal to 500 microns or a droplet size of greater than 100 microns.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-7, 9-13, 15-17, 20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenn, Jr et al. (WO 9625144, equivalent to US 6,080,708), in view of Tsaor (US 6,395,690, PTO-892) .

Glenn, Jr et al. teaches the process for making a cleansing/moisturizing dual composition (a wet-skin treatment composition) which is an oil-in-water emulsion, wherein (a) an aqueous phase comprising water and dispersion stabilizer such as trihydroxystearin having the formula (i) (according to the formula therein, the molecular weight is deemed lower than 1000 Daltones and capable of forming a network in the aqueous phase), which is a fatty acid ester or C14-C22 acyl derivative as the instantly claimed, or silicas (see US 6,080,708, abstract; col.4, line 46 to col.6) or polymeric stabilizers herein; (b) a structured oil phase (a lipid phase) comprising triglycerides and a structurant in about 75% by wt of that forms a stable 3-dimentional network comprising solid fatty esters, fatty alcohols, wax, petrolatum, with droplet size 0.1-100 microns, having viscosity within the instant claimed (see col.10-16). Glenn et al. also teaches that the aqueous phase of oil-in-water emulsion comprises from about 1 part to about 30 parts of surfactant selected from the group consisting of anionic surfactants, nonionic surfactants, cationic surfactants, amphoteric surfactants, and mixtures thereof.

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The emulsions containing 0.5 parts to 8 parts C8-C14 soap i.e anionic surfactant wherein the soap has a counterion selected from K and N(CH₂CH₂OH)₃, in addition to synthetic surfactant such as amphoteric, nonionic, and cationic are taught as preferred embodiments. See abstract; column 6, lines 3-60; column 7, lines 44-49; column 24, claim 20-24. It is also disclosed, that the preferred size of lipid droplets within the emulsion ranges from 0.1-100 microns. See column 13, lines 59-60. An oil-in-water composition comprising structurants, myristic alcohol, petrolatum; oil such as liquid hydrogenated polyisobutene, liquid cottonseed; organic dispersion stabilizer, trihydroxystearin is disclosed. See column 18, Examples 1-4.

Glenn, Jr et al. also clearly teaches the stepwise process for making the composition therein (see col 17, lines 25-65), including measuring skin retention and emulsions tests at 35 °C (see col.16, line 40-col.17, line 23). The reference also teaches that antimicrobial agents (preservative) and EDTA (chelating agent) and an essential oil are used. See col. 9, line 49 - col.10, line 37; col. 17, lines 42-45. See instant claims 37-38.

Glenn, Jr et al. does not expressly disclose the step of passing structured oil-in-water predispersion through a screen having an opening of up to about 2000 micrometers as claimed herein.

Tsuar teaches a process for making aqueous liquid cleanser compositions containing large oil droplets by passing the cleanser through a screen or screens having specific size of openings. It is taught that the size of oil droplets in the composition therein can be easily controlled by the number of screens and the size of the opening

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on the screen. An in-line screen process for making compositions containing oil droplets with the size in the range of 20 to 5000 micrometers is taught. See abstract; column 2, lines 40-50.

It would have been obvious to a person of ordinary skill in the art at the time the invention to pass oil-in-water predispersion through a screen having an opening of up to about 2000 micrometers to make the wet skin treatment composition because 1) Tsuar teaches that cleansing compositions containing oil droplets of specific droplet size are obtained by passing the predispersion through screen or screens having screens opening of different sizes.

Thus, One having ordinary skill in the art at the time the invention was made would have been motivated to pass oil-in-water predispersion of Glenn et al. through a screen having an opening of up to about 2000 micrometers with reasonable expectation of obtaining a wet skin treatment oil-in-water composition with lipid droplet size in the range taught by Glenn et al., i.e 0.1-100 microns. Note that Glenn teaches that the preferred size of lipid droplets within the emulsion ranges from 0.1-100 microns.

Furthermore, the combined teachings of Glenn et al., and Tsuar renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely foam volume of less than 5 cc, are inseparable from its composition. Note that the emulsions taught by Glenn et al. contain preferably 0.5 parts to 8 parts C8-C14 soap i.e anionic surfactant wherein the soap has a counterion selected from K and N(CH₂CH₂OH)₃ i.e less than 1 % anionic surfactant as in instant claim 22. Therefore, if the prior art teaches the

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composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Response to Applicant's Arguments:

Applicant's arguments with respect to rejections of claims under 35 U.S.C 103(a) made in the final office action have been considered but are moot in view of the new ground(s) of rejection necessitated by applicant's amendment which are adequately addressed by the obvious rejection presented above, and those found below.

Applicant argues that "'708 discloses no screening step, does not form large drop oil in the emulsion and provides no reason for one of ordinary skill in the art to want to screen such compositions. There is simply no reason, except in hindsight (and even there, it is not clear what the benefit would be) to use a screening process step in the '708". This argument has been considered, but not found persuasive because Glenn et al. teaches that the size of the lipid droplets within the emulsion ranges from 0.1 microns to 100 microns, and further teaches that the size is an important factor for lipid deposition on the skin. Tsuar teaches a process for making aqueous liquid cleanser compositions containing large oil droplets by passing the cleanser through a screen or screens having specific size of openings. It is taught that the size of oil droplets in the composition therein can be easily controlled by the number of screens and the size of the opening on the screen. Accordingly, one of ordinary skill in the art at the time of

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invention was made would have been motivated to pass oil-in-water predispersion of Glenn et al. through a screen having an opening of up to about 2000 micrometers with reasonable expectation of obtaining a wet skin treatment oil-in-water composition with preferred lipid droplet size of 0.1-100 microns as taught by Glenn et al., i.e 0.1-100 microns. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant's argues that "Referring again to the '690 reference, this clearly relates to cleanser compositions (comprising 5 to 35% surfactant) and not to wet-skin compositions which must have less than 1% anionic." This argument has been considered, but not found persuasive because '690 reference teaches that the cleanser compositions are employed for wet-skin treatment. See column 13, lines 25-65; column 15, Example 2; wherein wet-skin treatment method is taught for the compositions.

Applicant argues that "both these references relate to different compositions (higher foaming, cleanser compositions); it would not be obvious to combine one with the other (e.g., '708 has smaller oil particles and would not require screening)". This argument has been considered, but not found persuasive because 1) Glenn et al. teach

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that the size is an important factor for lipid deposition on the skin for skin cleansing oil-in-water composition, and 2) Tsuar teaches a process for making aqueous liquid cleanser compositions containing oil droplets 20 to 5000 micrometers by passing the cleanser through a screen or screens having specific size of openings. Accordingly, one having ordinary skill in the art at the time the invention was made would have been motivated to pass oil-in-water predispersion of Glenn et al. through a screen having an opening of up to about 2000 micrometers with reasonable expectation of obtaining a wet skin treatment oil-in-water composition with lipid droplet size in the range taught by Glenn et al., i.e 0.1-100 microns.

Claims 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenn, Jr et al. (WO 9625144, equivalent to US 6,080,708), in view of Tsaur as applied to claims 4-7, 9-13, 15-17, 20, 22-23 above, and further in view of Lochhead et al. (US 5,004,598, PTO-1449).

Glenn, Jr et al. as discussed above teaches the process for making a cleansing/moisturizing dual composition (a wet-skin treatment composition) which is an oil-in-water emulsion, wherein (a) an aqueous phase comprising water and dispersion stabilizer such as trihydroxystearin, or silicas or polymeric stabilizers herein; (b) a structured oil phase (a lipid phase) comprising triglycerides and a structurant in about 75% by wt of that forms a stable 3-dimentional network comprising solid fatty esters , fatty alcohols, wax, petrolatum, with droplet size 0.1-100 microns, having viscosity within the instant claimed. Glenn et al. also teaches that the aqueous phase of oil-in-

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water emulsion comprises from about 1 part to about 30 parts of surfactant selected from the group consisting of anionic surfactants, nonionic surfactants, cationic surfactants, amphoteric surfactants, and mixtures thereof.

Glenn et al. does not teach the process for making a cleansing/moisturizing composition without a surfactant.

Lochhead et al. teach a process for making cleansing/moisturizing oil-in-water emulsions without a surfactant, having a droplet size of 10 to 100 microns, comprising an (a) aqueous phase comprising water and a polymeric dispersion stabilizer, copolymer of acrylic acid, long chain acrylate; (b) oil phase comprises triglycerides, structurant such as petrolatum, fatty alcohol. See claims 1, 5, column 14-15; column 12, EXAMPLE column 3, lines 48-55; column 9, lines 30-33. It is also disclosed that the polymeric stabilizer can function as primary emulsifier or surfactant, and thus the composition can be made without conventional surfactants. See column 9, lines 34-37. It is further taught that these compositions made devoid of surfactant will have greater adhesion of the barrier oil to skin, and protection against skin irritants. See column 3, lines 13-18; column 4, lines 36-41.

It would have been obvious to a person of ordinary skill in the art at the time of invention to prepare a wet-skin treatment composition without a conventional surfactant.

One of ordinary skill in the art at the time of invention would have been motivated to prepare a skin-treatment composition as taught by Glenn without a surfactant because Lochhead teaches the process of making similar oil-in-water cosmetic composition without a conventional surfactant.

One of ordinary skill in the art at the time of invention would have been motivated to prepare a skin-treatment composition without any conventional surfactants with the expectation of obtaining a cosmetic composition which will have greater adhesion of the barrier oil to skin, and greater protection against skin irritants.

Response to Arguments:

Applicant argues that "as with the '708 reference, there is no reason or problem solved to suggest use of a screening method in Lochhead because there is no issue of large size particles and no problem in need of addressing". This argument has been considered, but not found persuasive because Lochhead reference was employed for its teachings of a process of making oil-in-water cosmetic composition similar to Glenn et al. without a conventional surfactant.

Glenn, Jr et al. as discussed above teaches the process for making a cleansing/moisturizing dual composition (a wet-skin treatment composition) which is an oil-in-water emulsion, and also teaches that the size is an important factor for lipid deposition on the skin for skin cleansing oil-in-water composition. Tsuar teaches a process for making aqueous liquid cleanser compositions containing oil droplets 20 to 5000 micrometers by passing the cleanser through a screen or screens having specific size of openings. Lochhead teaches a process of making oil-in-water cosmetic composition similar to Glenn et al. without a conventional surfactant, and teaches the advantages for the compositions therein. From, the teachings of Lochhead, one of ordinary skill in the art at the time of invention would have been motivated to prepare a skin-treatment composition taught by Glenn et al. without any conventional surfactants

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with the expectation of obtaining a cosmetic composition which will have greater adhesion of the barrier oil to skin, and greater protection against skin irritants. Further, from the teachings of Tsuar, one having ordinary skill in the art at the time the invention was made would have been motivated to pass oil-in-water predispersion through a screen having an opening of up to about 2000 micrometers with reasonable expectation of obtaining a wet skin treatment oil-in-water composition with lipid droplet size in the preferred range taught by Glenn et al., i.e 0.1-100 microns.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

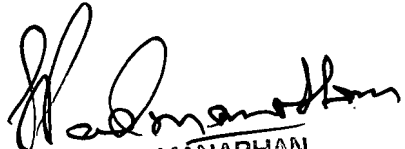
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Tuesday-Thursday, 8.00 am-3.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER